



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. FDA-2012-F-0728]

Representative Edward J. Markey; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Representative Edward J. Markey has filed a petition proposing that the food additive regulations be amended to no longer provide for the use of Bisphenol A (BPA)-based epoxy resins as coatings in packaging for infant formula because these uses have been abandoned. FDA expressly requests comments on the petitioner's request.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-F-0728 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-F-0728. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

## I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), notice is given that a food additive petition (FAP 2B4791) has been filed by Representative Edward J. Markey, House of Representatives, 2108 Rayburn House Office Building, Washington, DC 20515-2107. The petition proposes to amend the food additive regulations in § 175.300 (21 CFR 175.300) to no longer provide for the use of BPA-based epoxy resins as coatings in packaging for infant formula because these uses have been intentionally and permanently abandoned. BPA-based epoxy resins are formed by the reaction of 4,4'-isopropylendiphenol (i.e., BPA), and epichlorohydrin.

## II. Abandonment

Under section 409(i) of the FD&C Act, FDA "shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." FDA's regulations specific to administrative actions for food additives provide as follows: "The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive." (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide: "Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or appeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions."

(§ 171.130(b)). Under these regulations, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that the regulatory authorization is no longer necessary because the use of the food additive has been abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The petition submitted by Representative Markey contains public information and information collected from a survey of the U.S. registered manufacturers of infant formula to support the petitioner's claim that all U.S. infant formula manufacturers have abandoned the use of BPA-based epoxy resins as coatings in all food contact packaging for infant formula. According to the petition, these companies accounted for 100% of the current infant formula market in the United States.

FDA expressly requests comments on the petitioner's request that FDA amend the food additive regulations to no longer permit the use of BPA-based epoxy resins as coatings in packaging for infant formula. For the purposes of this petition, FDA considers the use of BPA-

based epoxy resins as coatings (as described in § 175.300(a)) in packaging of infant formula to mean a metal substrate (single use) or any suitable substrate (repeated use) being coated with BPA-based epoxy resins as a continuous film or enamel, serving as a functional barrier between the infant formula (powder or liquid) and the substrate. As noted, the basis for the proposed amendment is that the use of BPA-based epoxy resins as coatings in packaging for infant formula has been permanently and completely abandoned. Accordingly, FDA requests comments that address whether these uses of BPA-based epoxy resins have been completely abandoned, such as information on whether infant formula packaging containing BPA-based epoxy resins as coatings is currently being introduced or delivered for introduction into the U.S. market. Further, FDA requests comments on whether the uses that are the subject of the petition (BPA-based epoxy resins as coatings in infant formula packaging) have been adequately defined. FDA is not aware of information that suggests continued use of BPA-based epoxy resins as coatings in packaging for powder or liquid infant formula. FDA is providing the public 60 days to submit comments. FDA anticipates that some interested persons may wish to provide FDA with certain information that they consider to be trade secret or confidential commercial information (CCI) that would be exempt under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to FDA as CCI or trade secret by clearly marking both the document and the specific information as “confidential.” Information so marked will not be disclosed except in accordance with the Freedom of Information Act (5 U.S.C. 552) and FDA’s disclosure regulations (21 CFR part 20). For electronic submissions to <http://www.regulations.gov>, indicate in the “comments” box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as

confidential for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

FDA is not requesting comments on the safety of these uses of BPA-based epoxy resins as coatings because, as discussed previously, such information is not relevant to establishing abandonment as the basis of the proposed action. Any comments addressing the safety of BPA-based epoxy resins or containing safety information on these resins will not be considered in FDA's evaluation of this petition. Separate from FDA's consideration of this petition, FDA is actively assessing the safety of BPA (see 75 FR 17145, April 5, 2010; see also <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>).

FDA has determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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